



**Interagency Coordinating Committee on  
the Validation of Alternative Methods**

# **U.S. Strategy for Implementing the Vision for Regulatory Toxicity Testing in the 21<sup>st</sup> Century**

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Alternative Toxicological Methods (NICEATM)

National Institute of Environmental Health Sciences

SACATM Meeting, September 27, 2016  
Research Triangle Park, NC

Agency for Toxic Substances and Disease Registry • Consumer Product Safety Commission • Department of Agriculture  
Department of Defense • Department of Energy • Department of the Interior • Department of Transportation  
Environmental Protection Agency • Food and Drug Administration • National Institute for Occupational Safety and Health  
National Institutes of Health • National Cancer Institute • National Institute of Environmental Health Sciences  
National Library of Medicine • Occupational Safety and Health Administration

- **Ethics**



- **Efficiency**



- **Public Health (Human Relevance)**



# We must....

- Clearly define the objective and maintain focus
- Frame the discussion in a manner that can lead to a productive outcome

# This is not....

- An indictment of existing methods, practice, or policy
- An attempt to replace animal-based tests in the absence of suitable alternatives
- A discreditation of animal models used for biomedical research



Subcommittee Hearing

## Hearing on FY2017 National Institutes of Health Budget Request

Labor, Health and Human Services, Education, and Related Agencies

**Date:** Thursday, April 7, 2016

**Time:** 10:00 AM

**Location:** Dirksen Senate Office Building 138

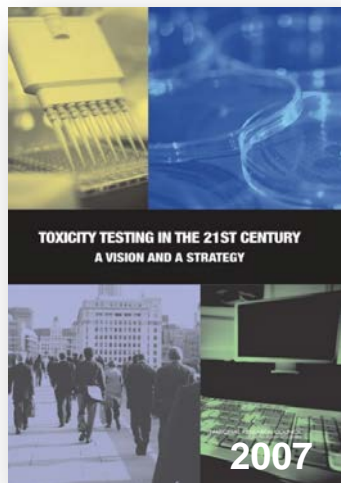
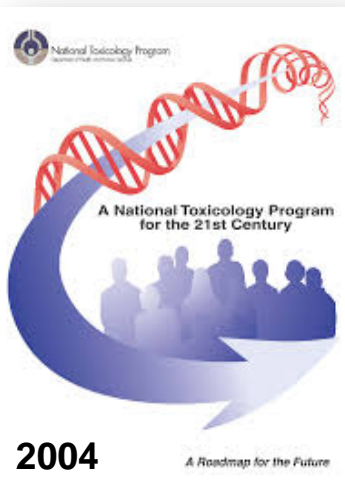


In Francis Collins' recent testimony to the congressional subcommittee with NIH budget oversight responsibility, he offered that :

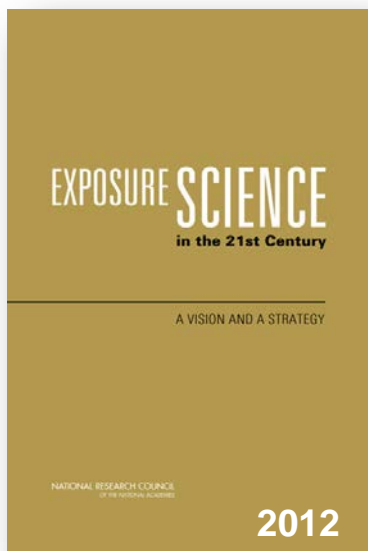
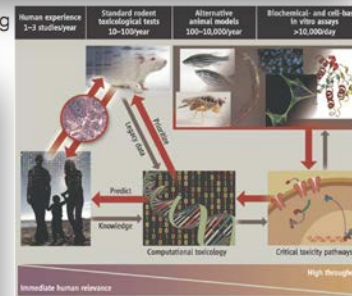
“Animal safety testing for environmental chemicals and drugs will largely be replaced by tissue chips and iPS cells in 10 years.”

“.....giving results that are more accurate, at lower cost and higher throughput.”





15 FEBRUARY 2008 VOL 319 SCIENCE www.sciencemag.org



## REVIEW ARTICLE

2014

### A 21st century roadmap for human health risk assessment

Timothy P. Pastoor<sup>1</sup>, Ammie N. Bachman<sup>2</sup>, David R. Bell<sup>3</sup>, Samuel M. Cohen<sup>4</sup>, Michael Dellarco<sup>5</sup>, Ian C. Dewhurst<sup>6</sup>, John E. Doe<sup>7</sup>, Nancy G. Doerrler<sup>8</sup>, Michelle R. Embry<sup>9</sup>, Ronald N. Hines<sup>9</sup>, Angelo Moretto<sup>10</sup>, Richard D. Phillips<sup>2</sup>, J. Craig Rowlands<sup>11</sup>, Jennifer Y. Tani<sup>8</sup>, Douglas C. Wolf<sup>12</sup>, and Alan R. Boobis<sup>12</sup>

<sup>1</sup>Syngenta Ltd., Greensboro, NC, USA, <sup>2</sup>ExxonMobil Biomedical Sciences, Inc., Annandale, NJ, USA, <sup>3</sup>European Chemicals Agency, Helsinki, Finland, <sup>4</sup>Department of Pathology and Microbiology, University of Nebraska Medical Center, Omaha, NE, USA, <sup>5</sup>Eunice Kennedy Shriver National Institute of Child Health and Human Development, Bethesda, MD, USA, <sup>6</sup>UK Chemicals Regulation Directorate, Kings Pool, York, UK, <sup>7</sup>Parker Dow Partnership LLP, Frodsham, Cheshire, UK, <sup>8</sup>ILSI Health and Environmental Sciences Institute, Washington, DC, USA, <sup>9</sup>US Environmental Protection Agency, ORD, NHEERL, Research Triangle Park, NC, USA, <sup>10</sup>Department of Biomedical and Clinical Sciences, University of Milan, Milan, Italy, <sup>11</sup>The Dow Chemical Company, Midland, MI, USA, and <sup>12</sup>Imperial College London, Hammersmith Campus, London, UK

Crit Rev Toxicol, 2014; 44(53): 1-5

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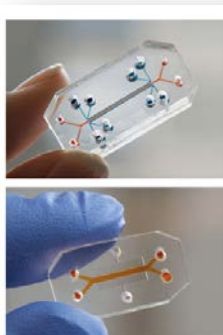
## 2016: Incorporating 21<sup>st</sup> Century Approaches into Risk Based-Science



### THE PRECISION MEDICINE INITIATIVE



# It is difficult for evolving institutional practices to keep pace with revolutionary advances in science and technology

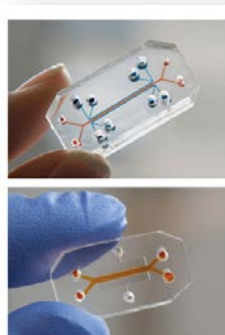


Wyss Institute researchers and a multidisciplinary team of collaborators seek to build and link 10 human organs-on-chips to mimic whole body physiology. The system will incorporate the Institute's Human Lung-on-a-Chip (top) and Human Gut-on-a-Chip (bottom).





# Technology is not self-implementing, obstacles are not self-resolving



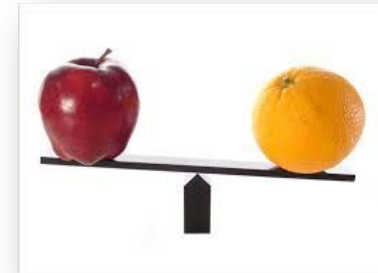
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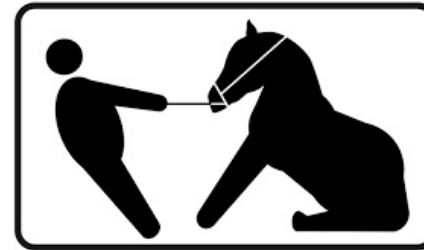




- **Animal Models as Gold Standard**



- **Institutional Resistance**



- **Harmonization**



## Developing a US Strategy and Roadmap

- ICCVAM is developing a short-term strategy to replace six commonly used animal toxicity tests (“EPA 6-pack”) within three years
- Implementing a more holistic, human-relevant, approach for toxicity testing in the 21<sup>st</sup> Century will require significant changes in policy, practice, and regulation; a challenge so complex and broad in scope that it cannot adequately be addressed by any single agency or existing government entity